

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov

SPL technical questions? Send to spl@fda.hhs.gov

UNII or SRS questions? Send to fda-srs@fda.hhs.gov

Agenda:

Downstream Uses of SPL (Tom Bizarro, First DataBank)

- First Databank – compendium ; also a member of NCPDP
- We look at SPL all the time. Most compendium are making use of the SPL
- We use the data as a source of information for our drug information, as support of our clinical models
- Improvement of SPL – common goal of both organizations.
- Tens of thousands of consumers are affected every day by the information provided within SPL
- Availability of the UNII code has been of great value
- The structure of the XML helps us
- FDB models are used in clinical health settings in a real-time environment
- Timeliness of the information is critical – updates in the modules occur daily
- Q: were you aware that data is being used downstream for purposes like this?
Can you give more information on exactly what you are doing with the data?

For every product, you have to be able to move from a high level view of the information to lower levels of information. Looking at the clinical requirements for doing drug interaction information mining – the SPL can be very useful. We can get the information directly from the manufacturer. We are also able to link down to the ingredient level using the SPL. We can link to a therapeutic class (grouping like products, for instance)

- Depending on how the indexing of indications is done, it could be of great value to a compendium such as FDB.
- Addition of inactive ingredients UNII's has been very helpful.
- Hierarchical proprietary classes, ATC; HFS; USC classifications are all available to the customer.
- Information about pharmacologic class is another useful area.

Overview of SRS and SRS web search demonstration (Frank Switzer, FDA SRS) – Refer to the slide set for lots of useful background

Q: Shouldn't this kind of information be included in a chemical or CMC submission?

A: For new products under review by the FDA, the assignment of the UNII can be part of the review process. For older products, send a request directly to the SRS group.

- The UNII search tool can connect you to a tremendous amount of information, as it links into NLM's Drug Portal. That was one reason for hosting the UNII application on the NLM site.
- The site is getting approximately 1000 hits per week.
- The site has approximately 17,000 UNII's right now.

Q: Homeopathic substances seem to cause some difficulty in assigning a UNII, particularly the simple products such as SODIUM CHLORIDE.

A: This is due, in part, to the 'counter-ion list' and its validation rule. The list is based on an INN/USN system and provides a simple rule for detecting drug substances. Homeopathic substances don't fit into that system.

- The search functionality allows both left and right truncation using the asterisk (*).
- SRS is currently working on the inclusion of a large number of combination products and trade name references. Use the left truncation * to search for something like TRIZIVIR, as you'll actually be pulling up a term that has a synonym of COMPONENT OF TRIZIVIR that way.
- Microsoft Office Excel 2003 has a limit to the number of rows it can handle in a single worksheet. So there's actually two spreadsheets – one covering approximately A – S, and another covering T – Z.

Q: Is there any lag time between the values entered in the spreadsheet and their entry into the web application?

A: The transfer of terms is still a somewhat manual process. If you don't find a term in the web application, you can always try searching the spreadsheet as a backup.

- UNII's can now be found in the USP Dictionary. They will be available in upcoming Martindale and Merck publications.

Next meeting scheduled for:

Wednesday, Aug 25, 2010

Time: 1:00-2:30 ET

Dial-in info: number 1-877-423-2663 PIN# 517342

- Minutes of previous Process Team meetings are here:
<http://spl-work-group.wikispaces.com/Process+Communications+Forum>